UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,737	01/03/2007	Stephane Rioux	484112.436USPC	4671

500 7590 04/24/2009

SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 5400
SEATTLE, WA 98104

EXAMINER	
BASKAR, PADMAVATHI	
ART UNIT	PAPER NUMBER
1645	
MAIL DATE	DELIVERY MODE
04/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,737	RIOUX ET AL.	
	Examiner	Art Unit	
	Padma V. Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21,23-26,30-33 and 36-48* is/are pending in the application.

4a) Of the above claim(s) *25,26,30-33 and 44-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21,23,24 and 36-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/12/09* .
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

1. The amendment filed on 1/12/09 is entered.

Status of claims

2. Claims 1-20, 22, 27-29, 34-35 have been cancelled

Claims 21, 23, 30, 33, 36, 37, 40, and 42 have been amended

Claims 25-26, 30-33 and 44-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claims 21, 23, 24, 36 and 37-43 are under examination as drawn to an elected invention.

Information Disclosure Statement

3. The Information Disclosure Statement submitted on 1/12/09 is acknowledged and a signed copy of the same is attached to this Office action.

Claim Rejections - 35 USC 112, first paragraph maintained

4. The new matter rejection of claims 21, 24, 37, 42 and 43 under 35 U.5.C. 112, first paragraph is maintained for the same reasons as set forth in the previous Office action.

Applicant now amended the claim 21 to recite " wherein the two or more antigenic polypeptide fragments elicit an antibody that specifically binds to the polypeptide that consists of the amino acid sequence set forth as SEQ ID NO:2 and wherein the two or more antigenic polypeptide fragments induce an immune response against *Streptococcus pyogenes*". However, chimeric polypeptide as claimed has no clear support in the specification and in the claims as originally filed.

In the response filed on 1/12/09 applicant pointed to the examiner pages 16, 19, 20, 28, 31 ,32, 48, 54 , example 1 and 9 for support.

The suggested support is not found persuasive because the examiner reviewed the pages and found that the full length polypeptide SEQ ID NO:2/ SHB-GAS- 102 has support and found to be inducing an immune response against *Streptococcus pyogenes* but not the chimeric polypeptide as claimed. Further, the specification fails to show that the chimeric polypeptide comprising two or more fragments, each comprising 15 contiguous amino acids elicits an antibody that binds to the polypeptide SEQ ID NO:2. The subject matter claimed in claims 21, 24, 37, 42 and 43 broadens the scope of the invention as originally disclosed in the specification.

5. The written description rejection of claims 21, 23, 24, 36, 37, 38, 40, 42-43 under 35 U.5.C. 112, first paragraph is maintained for the same reasons as set forth in the previous Office action.

Applicant 1/12/09 states that instant claims satisfy the written description requirement and cites MPEP 2163. Applicant argues that SEQ.ID.NO:2 , the sequence that is 90% identical to SEQ.ID.NO:2 and fragments have been disclosed in the specification , pages 16, 18, 19, 48 . Working example 8 and

9 show that SEQ ID NO:2/ SHB-GAS induces antibody response and animals were protected against challenge upon passive immunization of antibodies.

Applicants arguments 1/12/09 are fully considered but has not been found persuasive because as applicant correctly states that SEQ ID NO:2/ SHB-GAS has been shown to induce antibodies and protected animals upon transfer of antibodies to animals. However, structural features that could distinguish a "chimeric polypeptide" in the genus from others in the protein class are missing from the disclosure and the claims. Further, the specification fails to correlate the structure /function relationship of representative number of species of chimeric polypeptide and/or an isolated polypeptide that is 90% identical to SEQ.ID.NO:2 induce an immune response against *S. pyogenes* . As indicated in the previous office action ,only the SEQ ID NO:2/ SHB-GAS polypeptide , but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph.

Applicant states that according to the state of the art as shown by Roitt et al , Lipman et al , Wan et al etc, different antibodies especially polyclonal antibodies bind to epitopes and functional variants that would retain immunogenicity can be screened and predictable. Applicant also states that a person skilled in the art could also use one of the many available methods for predicting specific antigenic determinants in a polypeptide sequence and cites Hopp , Hofmann et al, Jameson and Wolf,); Menendez et al, Thornton et al and Kolaskar and Kokolus et al.

Although applicant argues that it is routine in the art to generate fragments and to determine whether or not those fragments are immunogenic and bind to an antibody , the requirement of 35 USC 112 first paragraph is to show structure /function relationship of representative number of species of chimeric polypeptide (i.e., inducing an immune response against S. pyogenes). The claimed invention is not drawn to screening of molecules but the function is inducing an immune response against *S. pyogenes*. However, the screening assays suggested by applicant do not enable the claimed invention because the court found in *Rochester v. Searle*, 358 F.3d 916, Fed Cir., 2004 that screening assays are not sufficient to enable an invention since they are merely a wish or plan for obtaining the claimed chemical invention. Therefore, it is appropriate to maintain the rejection.

6. The scope of enablement rejection of claims 21,23, 24, 36,37, 38,40,42-43 under 35 U.5.C. 112, first paragraph is maintained for the same reasons as set forth in the previous Office action.

Applicant 1/12/09 states that the Office interpretation of "an amino acid sequence" is in correct and does not read on fragments . Applicant argues that a person skilled in the art knows how to make fragments without loss of function and cites several references (as cited in the response filed on1/12/09 in pages 23-26). Applicant also argues that the references cited by the examiner fail to reflect the predictability associated with identifying functional polypeptide variants.

Applicants arguments 1/12/09 are fully considered but has not been found persuasive because none of the cited art indicate that the antibodies generated to a chimeric polypeptide (i.e., fragments of

polypeptide that are linked) will bind to full length SEQ ID NO:2/ SHB-GAS and induce an immune response against *S. pyogenes* . Here , the issue is whether or not chimeric polypeptide induces an antibody which can recognize and bind to the full length polypeptide and at the same time protect against infection caused by *S. pyogenes*. The cited references by the examiner in the previous Office action indicated that it is not predictable to induce an antibody against fragment that can bind to the full length polypeptide . Since these antibodies did not bind to the polypeptide , one skilled in the art understands that the antibodies are not immunoreactive and is unpredictable to use them for immunotherapy (i.e., no function). In view of applicant's specification and the prior art cited by the examiner and applicant, it would require undue experimentation on the part of the skilled artisan to use the broadly claimed chimeric polypeptide or polypeptide having 90% identity to the SEQ ID NO:2 . Applicants comments with reference to "an amino acid sequence" are not relevant to the amended claims.

Claim Rejections - 35 USC § 102 maintained

7. The rejection of claims 21, 23 , 24 and 36- 43 under 35 U.S.C. 102(b) as being anticipated by Telford J et al WO200234771 is maintained for the same reasons as set forth in the previous Office action

The examiner regrets the typographical error for SEQ.ID.NO:6344 instead of SEQ.ID.NO:6346 in the previous Office action. However, the sequence cited in the action indicates that it is SEQ.ID.NO:6346.

Applicant 1/12/09 argues that Telford fails to teach or suggest a chimeric polypeptide ,antigenic fragments , isolated polypeptide SEQ ID NO:2 and a composition comprising said isolated polypeptide that induces an immune response against *S. pyogenes because* the cited reference teaches an hybrid protein that comprises a protein from any one of the hundreds of full-length polypeptides and not the chimeric polypeptide as claimed.

Applicants arguments are fully considered but has not been found persuasive because as discussed in the rejection Telford et al clearly disclose a polypeptide , SEQ.ID.NO:6346 which is 100% identical to the claimed polypeptide in addition to several hundreds of full-length polypeptides. As the art discloses that the term hybrid protein is associated with chimeric protein , the disclosed hybrid protein of SEQ.ID.NO:6346 reads on the chimeric protein that induces an immune response to *S.pyogenes* because the polypeptide is obtained from *S.pyogenes*. The specification , para 0264 recites that chimeric polypeptides comprising two or more polypeptides are linked as to form a chimeric polypeptide. Therefore, hybrid proteins as disclosed by the prior art read on the claimed invention. Similarly the teachings of Telford disclose pharmaceutical composition, kit comprising said SEQ.ID.NO:6346.

Applicant states that Telford fails as an anticipatory reference because the document fails to provide an enabling disclosure. Applicant points that a polypeptide related to SHB-GAS-102 is not disclosed.

Applicants arguments are fully considered but has not been found persuasive because applicant did not provide any evidence why Telford document is a non-enabling disclosure. Applicant uses the

term SHB-GAS-102 (claimed SEQ.ID.NO:2) for the disclosed polypeptide SEQ.ID.NO:6346 and both the polypeptides are 100% identical to each other. Briefly, the prior art discloses a composition comprising a polypeptide SEQ.ID.NO:6346 that is structurally 100% similar to the polypeptide present in the claimed pharmaceutical composition. Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

Applicant states that Telford provides more than 5,000 open reading frames that putatively encode polypeptides that are expressed by *S. pyogenes* and provides no more than a generalized statement with respect to how the various putatively encoded polypeptides disclosed therein may be used. Telford describes that each and every one of the polypeptides disclosed therein may be a useful antigen for a vaccine or a diagnostic. Given that only a few *S. pyogenes* antigens have been investigated as viable vaccine candidates *(see, e.g.,* specification at page 1, line 30 through page 2, line 20), a person skilled in the microbiology and vaccine arts would immediately understand that the statement in Telford provides no guidance with respect to which polypeptides disclosed therein may be capable of inducing an immune response against *S. pyogenes*.

Applicants arguments are fully considered but has not been found persuasive because Telford provides more than 5,000 polypeptides with structure . One such polypeptide was SEQ.ID.NO:6346 (Example 2053, page 2320 in the patent) that can be used for vaccine purposes. Given that the prior art fully discloses the polypeptide from *S.pyogenes*, one skilled in the microbiology and immunology art knows how to formulate the immunogenic composition comprising said polypeptide to induce an immune response. Again , products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

Remarks

9. No claims are allowed.

This application contains claims25-26, 30-33 and 44-48 drawn to an invention nonelected. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action

11. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 156, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571) 272-0956.

Respectfully,
/Padma Baskar /
Examiner, Art Unit 1645

/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645